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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,303	11/28/2000	Akihiko Sano	0020-4771P	8796

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EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/10/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

09/701,303

Applicant(s)

SANO ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination and Information Disclosure Statement filed on July 28, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujioka et al. (US 5851547) In combination with Hudson et al. (EP 0009410 A2). Fujioka teaches an implantable rod-like formulation comprising a non-disintegrating inner layer comprised of a biocompatible material in which a drug is uniformly dispersed and an outer layer comprised on a biocompatible material wherein the outer layer surrounds the inner layer and said outer layer is impermeable to water and capable of controlling the swelling of the inner layer (Col. 4, lines 50- 65). The outer layer is composed of a non-biodegradable polymer such as silicone polymer, preferably Dow

Corning MDX 4-4210 (Col. 5, lines 56-64). The inner layer is composed of water swelling material or non-swelling material that contains water swellable additives as well as a drug dispersed therein (Col. 6, lines 5-63). The composition can be formed into a rod-like shape selected from circular cylinders, prisms, or elliptical cylinders (Col. 7, lines 46-52). The layers take the form of concentric circles (Col. 7, lines 55-63). The inner layer is exposed to the environment at one end of the rod or at both ends of the rod (Col. 8, lines 50-56). The formulation achieves long-term zero-order release (Col. 8, lines 25-31). One or more drugs can be incorporated into said formulation (Col. 7, lines 53-63).

Fujioka does not expressly teach that the outer layer contains an active agent or drug.

Hudson teaches a solid, cylindrical, subcutaneous implantable formulation comprising a core and a coating containing a drug, namely estradiol (Page 1, lines 1-11). The inner core is coated with a dimethylpolysiloxane silicone rubber and estradiol to provide an optimum diffusion rate for estradiol to permit a substantially constant rate of administration (Page 4, lines 18-24). The preferred silicone rubber is Dow Corning MDX-4-4210 (Page 5, lines 1-4).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a multiple drug delivery system wherein the system is an implant comprising an inner core containing a drug and an outer layer containing a biologically, non-degradable hydrophobic polymer material and a drug wherein the implant is in the form of a rod with concentrically located layers.

One of ordinary skill in the art would have been motivated to do this to provide a multiple drug delivery system that provides a zero-order release profile over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection. While applicants argue that no motivation exists to incorporate a drug into the outer layer of Fujioka, it is the position of the Examiner that the secondary reference teaches an active agent can be incorporated in such a layer. The secondary reference uses the same exact silicone rubber to deliver a drug. It is quite clear that the prior art shows a drug can be release over an extended period of time from a water impermeable outer layer. Fujioka teaches that multiple drugs can be delivered. When combined with Hudson, the references render obvious a system in which a formulation can release an drug from the inner and outer core while maintaining its shape so can to control the swelling of the inner layer. Therefore, applicants' arguments to the contrary are not persuasive.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 7, 2003

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER